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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/785,761	02/16/2001	Grace Yim Ngan Chan		2972

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805 THIRD AVENUE
NEW YORK, NY 10022

[REDACTED] EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

[REDACTED] ART UNIT

[REDACTED] PAPER NUMBER

1753

DATE MAILED: 08/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/785,761	CHAN ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 27 May 2003.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) 7-13 and 21 is/are allowed.
- 6) Claim(s) 1-6, 14-20 and 22 is/are rejected.
- 7) Claim(s) 8 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 16 February 2001 is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ |

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Response to Amendment

1. Applicant's amendment of May 27, 2003 does not place the application in condition for allowance. Independent claims 1 and 14 have been amended to require that the polyacrylamide gel be a non-stacking polyacrylamide gel. The examiner does not see how this limitation structurally (or compositionally) modifies the claimed gel; it is only an intended use limitation. If Balshüsemann's polyacrylamide stacking (collecting) gel is otherwise the same as Applicant's claimed gel then it is also capable of the same use; that is, it is capable of being used as a stacking or non-stacking gel. A individual gel slab by itself is neither a stacking gel nor a separating gel. In fact, to create a stacking zone only a gel discontinuity, usually a change in porosity, and a pH discontinuity between two adjacent gel slabs is needed.^{1,2} In this case Balshüsemann has chosen to use the gel for stacking.

Furthermore, Balshüsemann's non-stacking (separating) gel clearly meets Applicant's limitations in claims 1 and 14. As seen on page 6 of the English language translation of Balshüsemann, provided herewith, the non-stacking (separating) gel compromises polyacrylamide gel with 0.25M tris tritratated with HCl. Although the pH is 7.6 in this *example* embodiment, pH 7.6 is only slightly outside of the claimed range of 6.5 to 7.5. In any event, from claim 4 and the last paragraph on page 3, bridging to page 4, of the English language translation of Balshüsemann it is apparent that a pH range of 7.2-8.4 is contemplated. Indeed

¹ Pages 79-81 of Electrophoresis: Theory, Techniques, and Biochemical and Clinical Applications, 2nd ed., Anthony Andrews, Clarendon Press-Oxford, 1986.

² Column 3, lines 20-45 of Starr (US 5,660,702).

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using identical buffers at pH 7.5 in the stacking and non-stacking gels is disclosed in the cited passages.

Claim Objections

2. Claim 8 is objected to because of the following informalities: in line 4 "or" should be and -- and "using," should be -- using --.
3. Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. Claim 22 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Is the concentration of both Tris and HEPES in the range of 0.05 to 0.125 M?

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-6 and 14-20 are rejected under 35 U.S.C. 102(b) as being anticipated by an English language translation of Balshüsemann (DE 4112168 A1), hereafter “Balshüsemann”.

Addressing claims 1 and 14, the collecting gel for an electrophoresis apparatus described on page 6 of Balshüsemann comprises polyacrylamide gel and tris(hydroxymethyl)aminomethane at a concentration of 0.25M titrated with hydrochloric acid to a pH of 6.7. That independent claim 1 has been amended to require that the polyacrylamide gel be a non-stacking polyacrylamide gel does not structurally or compositionally modify the claimed gel; it is only an intended use limitation. If Balshüsemann’s polyacrylamide stacking (collecting) gel is otherwise the same as Applicant’s claimed gel then it is also capable of the same use; that is, it is capable of being used as a stacking or non-stacking gel. A individual gel slab by itself is neither a stacking gel nor a separating gel. In fact, to create a stacking zone only a gel discontinuity, usually a change in porosity, and a pH discontinuity between two adjacent gel slabs is needed.^{3,4} In this case Balshüsemann has chosen to use the gel for stacking.

³ Andrews, *ibid.*

⁴ Starr, *ibid.*

Additionally, the separating (non-stacking) gel described in claim 4 and at the bottom of page 3 of Balshüsemann, bridging to page 4, meets Applicant's claim limitations.

Addressing claims 2, 3, 15, and 16 at the bottom of page 3 of Balshüsemann, bridging to page 4, a tris concentration of 0.1-0.5 M is disclosed as is a pH range of 7.2 to 8.4.

Addressing claims 4-6 and 17-19, since Applicant's claimed gels are compositionally within the scope of the gels disclosed by Balshüsemann their properties should be the same.

Addressing claim 20, Applicant's steps of applying a sample and subjecting the gel to an electric field may be found on page 5 of Balshüsemann.

Allowable Subject Matter

7. Claims 7-13 and 21 are allowed.

8. Claim 22 would be allowable if rewritten to overcome the rejection under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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9. The following is a statement of reasons for the indication of allowable subject matter:

- a) Claim 7: the prior art of record does not disclose a method of preparing polyacrylamide gel by polymerizing acrylamide in the presence of a cross-linking agent, water, and the specified Tris buffer system;
- b) Claims 8-13 depend directly or indirectly from allowable claim 13;
- c) Claim 21: the prior art of record does not disclose a polyacrylamide gel comprising the specified Tris buffer system; and
- d) Claim 22 depends from allowable claim 21.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (703) 308-3322. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

Alex Noguerola

Alex Noguerola

August 5, 2003